

## REMARKS

The disclosure has been objected to on page 1 requiring as updating of the current status of the predecessor applications.

The citations of the predecessor applications appearing in the specification on page 1 have been updated, as set forth in the SPECIFICATION portion of the attached APPLICATION REVISIONS. As amended, it is submitted that the citations of the predecessor applications are correct up to the date hereof, and that the disclosure in this application as amended is therefore not objectionable.

Claims 49, 50, 54, 55, 60, 61 and 63-66 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite regarding the designated terms “endoscope” and “comprising”.

Applicant has amended these claims in consideration of the Examiner's analyses, comments and suggestions to correct the recitations in the dependent claims of ‘comprising’ to read --further comprising--, and ‘instrument’ to read --endoscope--, as well as to correct a few inadvertent typographical errors appearing in claim 63. It is therefore respectfully submitted that these claims as amended now amply define the invention with sufficient particularity and distinctiveness to be patentable to Applicant.

Claims 57 [sic-47?]-55 and 57-62 have been previously rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 8, 14, 19, 33 and 47-53 of co-pending application Serial No. 09/475,789. This rejection is respectfully traversed.

Claims 8, 33, 50, and 52 of application Serial No. 09/475,789 have been cancelled. The provisional rejection of claims 47-55 and 57-62 for obviousness-type double patenting over the pending claims 14, 19, 47-49, 51, and 53 of application Serial No. 09/475,789 is respectfully traversed.

There does not appear to be a direct claim-to-claim correlation that can be specified between the rejected claims of the current application and the referenced claims of the pending '789 application. However, Applicant submits that separate, patentably distinguishable inventions are defined by these sets of claims of the respective applications. More specifically, the cited claims of the '789 application are specifically limited by recitations of a surgical procedure in which a medical instrument is advanced within the circulatory system or vessel of a patient, and is further advanced from within the circulatory system or vessel to outside thereof in the course of a bypass grafting procedure.

In contrast, the cited claims of the current application are specifically directed to forming an opening or arteriotomy in a target blood vessel to which a grafting vessel may be anastomosed and, contrary to the Examiner's contention, the present claims cannot be "read on" (as in 'dominated' by?) the targeted claims of the '789 application since these latter claims are specifically limited by the

recitations of intravascular activity, not recited in the present claims. Thus, the Examiner correctly identifies the present claims as broader, and it is submitted that the subject matter and the recitations thereof in the target claims of the '789 application do not even establish a *prima facie* basis from which a proper determination of obviousness of the present claims can be made. It is therefore respectfully submitted that the subject claims of the present invention are patentably distinguishable over the targeted claims as currently pending in the '789 application.

Claims 47-60 and 62-66 have been rejected under the judicially-created doctrine of obviousness-type double patenting over the claims 1-40 of U.S. Patent 5,211,683. This rejection is respectfully traversed.

These claims of the current application distinctively recite endoscopic procedures for forming an opening in a blood vessel and for forming an anastomosis between a conduit or graft and the blood vessel. Additionally, these claims also distinctively define a procedure for locating an end of a conduit or graft vessel near a blood vessel and for manipulating a surgical device within a lumen of an instrument for forming an arteriotomy in the blood vessel and an anastomosis therewith with an end of the conduit or graft vessel. Further, these claim distinctly define surgical procedures for installing an expandable stent in an artery to attach a graft vessel to the artery. The dependent claims are further limited by various

additional recitations of a vessel being the aorta, expanding the stent radially, positioning the conduit or graft vessel through the lumen of an endoscope, and the like.

In contrast, claims 1-40 of '683 patent include recitations, for example, of "the upstream site is covered by the substantially intact portion of the epidermis of the body." In consideration of these recitations, Applicant respectfully submits that these claims do not "read on" the subject claims 47-60 and 62-66, and that such a 'test' is not sufficient to make a proper determination of obviousness anyway. Specifically, the claims 1-40 of the '683 patent fail to establish even a *prima facie* basis from which to make a proper determination of obviousness of the subject matter distinctively claimed in the subject claims 47-60 and 62-66. It is therefore respectfully submitted that claims 47-60 and 62-66 define distinctively patentable subject matter over the claims 1-40 of the '683 and that the double patenting rejection should therefore be withdrawn.

Claims 47-60 have been rejected under the judicially-created doctrine of obviousness-type double patenting over the claims 1-4 of the '375 patent. This rejection is respectfully traversed.

These claims of the current application distinctively recite endoscopic procedures for forming an opening in a blood vessel and for forming an anastomosis between a conduit or graft and the blood vessel. In addition, the

dependent claims are further limited by such specific recitations as positioning the conduit through an entry below the inguinal ligament, and advancing the conduit through the lumen of an instrument having an end positioned near a selected blood vessel.

In contrast, the claims 1-4 of the '375 patent include recitations of, for example, an expandable stent. In consideration of such recitation, Applicant respectfully submits that these claims do not "read on" the subject claims 47-60, and that such a 'test' is not sufficient to make a proper determination of obviousness anyway. Specifically, the claims 1-40 of the '683 patent fail to establish even a *prima facie* basis from which to make a proper determination of obviousness of the subject matter distinctively claimed in the subject claims 47-60. It is therefore respectfully submitted that claims 47-60 define distinctively patentable subject matter over the claims 1-4 of the '375 patent, and that the double patenting rejection should therefore be withdrawn.

Claims 47-60 and 62-66 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-13 of the '220 patent. This rejection is respectfully traversed.

These claims of the current application include distinctive recitations, for example, as discussed in the above Remarks.

In contrast, the claims 1-13 of the '220 patent include various recitations of, for example, suturing one end of the graft. In consideration of such recitation, Applicant respectfully submits that these claims do not "read on" the subject claims 47-60 and 62-66, and that such a 'test' is not sufficient to make a proper determination of obviousness anyway. Specifically, the claims 1-13 of the '220 patent fail to establish even a *prima facie* basis from which to make a proper determination of obviousness of the subject matter distinctively claimed in the subject claims 47-60 and 62-66. It is therefore respectfully submitted that these claims define distinctively patentable subject matter, and that the double patenting rejection should therefore be withdrawn.

Claims 47-60 and 62-66 have been rejected under the judicially-created doctrine of obviousness-type double patenting over the claims 1-15 of the '167 patent. This rejection is respectfully traversed.

These claims of the current application include distinctive recitations, for example, as discussed in the above Remarks.

In contrast, the claims 1-15 of the '167 patent include various recitations of, for example, the second location exposed through an incision in the body. In consideration of such recitation, Applicant respectfully submits that these claims do not "read on" the subject claims 47-60 and 62-66, and that such 'test' is not sufficient to make a proper determination of obviousness anyway. Specifically, the

claims 1-15 of the '167 patent fail to establish even a *prima facie* basis from which to make a proper determination of obviousness of the subject matter distinctively claimed in the subject claims 47-60 and 62-66. It is therefore respectfully submitted that these claims define distinctively patentable subject matter, and that the double patenting rejection should be withdrawn.

Claims 47, 51 and 62 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kensey '612. This rejection is respectfully traversed.

These claim specifically recite in various ways “endoscopically forming an anastomosis between the blood-conveying conduit and the blood vessel at the selected location”.

This aspect of the claimed invention promotes the attachment of one vessel (a graft) to another vessel, and is to be performed in order to provide a conduit for blood flow out of the vessel and through the graft.

In contrast, this aspect of the claimed invention is clearly lacking in the disclosure of Kensey '612 which is directed to device and method for closing off a puncture or other opening in a blood vessel, and for hemostatically sealing the puncture (col. 2, lines 18-34). There is not a scintilla of suggestion found in this reference about performing anastomosis over/about a vessel opening to promote blood flow from the vessel through such opening and through an anastomosed graft vessel, in any way resembling the medical procedure as claimed by

Applicant. At best, this reference merely plugs a puncture or incision in a vessel and offers no hint or suggestion of anastomosing a graft vessel to such a puncture.

It is therefore respectfully submitted that this reference substantially teaches away from Applicant's claimed invention, and its deficient disclosure does not anticipate the subject claims which instead are submitted to be patentably distinguishable over the reference.

Claims 48, 52-54 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kensey '612 above. This rejection is respectfully traversed.

These dependent claims are further restricted over the respective independent claims by specific recitations of the aorta, as the Examiner correctly observed, and additionally by specific recitations (in claims 53 and 54) of "the selected location is above the iliac arterial bifurcation of the aorta" and "anastomosing the end portion of the blood-conveying conduit to the selected location". And, these dependent claims are also restricted by the recitations in the respective independent claims of "forming an anastomosis between the blood-conveying conduit and the blood vessel at the selected location". For grafting (forming an anastomosis) as claimed, the aorta is particularly beneficial for the reasons as discussed, for example, at page 12, line 17 to page 13, line 27.

These aspects of the claimed invention are not shown or even suggested by Kensey '612 which merely plugs a vessel, and which is deficient of disclosure of



grafting techniques as claimed by Applicant. Nor does the disclosure in this reference of merely plugging a vessel in anyway satisfy the requirements for establishing a *prima facie* basis of each of the claimed limitations from which a proper determination of obviousness can be made. Additionally, there is insufficient or no instruction or motivation set forth in this reference for in any way modifying its objective and procedures for plugging a vessel to yield Applicant's claimed invention without impermissibly also destroying the functioning of this reference. It is therefore respectfully submitted that dependent claims 48 and 52-54 are patentably distinguishable over the deficient disclosure of Kensey '612.

Reconsideration and allowance of claims 47 to 424 pending in this application are solicited.

Respectfully submitted,  
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ATTACHMENT: APPLICATION REVISIONS

APPLICATION REVISIONS

In the Specification:

This application is a continuation of co-pending Application Serial No. 09/475,789, entitled "Extravascular Bypass Grafting Method Utilizing An Intravascular Approach", filed on December 30, 1999, which is a continuation of Application Serial No. 09/111,062, entitled "Method Of Securing A Prosthetic Device To A Patient's Circulatory System", filed on July 7, 1998, now is abandoned, which is a continuation of Application Serial No. 09/090,598, entitled "Bypass Grafting Method Which Uses A Number of Balloon Catheters To Inhibit Blood Flow To An Anastomosis Site", filed on June 4, 1998, now U.S. Patent No. 5,934,286, which is a continuation of Application Serial No. 09/073,336 entitled, "Method For Directing Blood Flow In The Body Of A Patient With A Graft And Stent Assembly", filed on May 5, 1998, now U.S. Patent No. 5,979,455, which is a continuation of Application Serial No. 08/702,742 entitled, "Method For Implanting An End Portion Of A Graft Within The Body Of A Patient During A Bypass Grafting Procedure", filed on August 23, 1996, now U.S. Patent No. 5,749,375, which is a continuation of Application Serial No. 08/391,960, entitled "Bypass Grafting Method", filed on February 21, 1995, now U.S. Patent No.

5,571,167, which is a continuation of Application Serial No. 08/138,912, entitled "Graft And Stent Assembly", filed on October 18, 1993, now U.S. Patent No. 5,456,712, which is a division of Application Serial No. 08/056,371, entitled "Method And Apparatus For Implanting A Graft Prosthesis In The Body Of A Patient", now U.S. Patent No. 5,304,220, which is a continuation-in-part of Application Serial No. 07/725,597, entitled "Method Of Implanting A Graft Prosthesis In The Body Of A Patient", filed on July 3, 1991, now U.S. Patent No. 5,211,683, which are all incorporated by reference herein in their entirety.

In the Claims:

49. (Amended) The medical procedure according to claim 48 further comprising:

positioning an end of an endoscope having a lumen therethrough near the selected location; and

advancing an end portion of the blood-conveying conduit through the lumen of the endoscope to the selected location.

54. (Amended) The medical procedure according to claim 52 further comprising:

positioning an end of the blood-conveying conduit near the arteriotomy at the selected location; and

anastomosing the end portion of the blood-conveying conduit to the selected location.

59. (Amended) The medical procedure according to claim 58 further comprising:

positioning an end of an endoscope having a lumen therethrough near the selected location; and

advancing an end portion of the blood-conveying conduit through the lumen of the endoscope to the selected location.

61. (Amended) The medical procedure according to claim 60 in which a femoral artery includes an occluding formation, and the initial entry of an end of the [instrument] endoscope is into the femoral artery at a location below the inguinal ligament, [and] further comprises:

directing the end of the instrument out of the femoral artery at a location intermediate the occluding formation and the initial entry for positioning near the selected location.

63. (Amended) A method of bypassing a restriction in an artery of a mammal, the method comprising:

providing a graft having a body portion with a first end[;], a second end and a lumen therebetween;

providing an expandable stent;

forming a first aperture in a first artery;  
forming a second aperture in a second artery distal of the restriction;  
placing the graft between the first aperture in the first artery and the second aperture in the second artery;  
inserting the expandable stent in the [final] first artery;  
deploying the stent to connect the first end of the graft within the first artery;  
and  
attaching the second end of the graft to the second aperture in the second artery.